

was to eliminate the complementary product of a rival.”) (emphasis added);<sup>8</sup> Herbert Hovenkamp, *Post-Chicago Antitrust – A Review and Critique*, 2001 Colum. Bus. L. Rev. 257, 332 (2001) (“[S]ignificant evidence that an innovation is an actual product improvement should result in dismissal of the complaint . . . the plaintiff should be required to show that the defendant set out to innovate a product that was not superior at all, but whose only result would be to destroy or serious[ly] injure the complementary technology of a rival or else to raise its costs.”).

**B. Plaintiffs Product Introduction Allegations Do Not State an Antitrust Claim.**

Based on the foregoing precedent, Plaintiffs’ Product Introductions allegations do not support a claim under the Sherman Act. First, Plaintiffs have not and cannot allege that any of the Defendants’ Product Introductions prevented anyone from bringing a saleable product to the market.<sup>9</sup> In sharp distinction, in cases even considering claims of wrongful innovation, those courts were faced with actual foreclosure. Typically, the challenged product change would completely foreclose a plaintiff from competing in a complementary market for a time because their product had become physically incompatible. For example, the new film only fit the new camera in *Berkey* and the peripheral computer equipment could not interface with the computer in the *IBM* cases. See *Berkey*, 603 F.2d at 270; *Transamerica*, 698 F.2d at 1380-81.

As Plaintiffs concede in the present case, the introduction of new TriCor products have not foreclosed Teva or Impax from selling a competitive product. Teva Counterclaims, ¶ 77. Plaintiffs

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<sup>8</sup> Professor Areeda’s treatise, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, is widely regarded as the authority on antitrust law, so much so that Justice Breyer observed: “No wonder that most practitioners would prefer to have two paragraphs of Areeda’s treatise on their side than three Courts of Appeals or four Supreme Court Justices.” Justice Stephen Breyer, *In Memoriam: Phillip E. Areeda*, 109 Harv. L. Rev. 889, 890 (1996).

<sup>9</sup> Teva and Reliant sell fenofibrate capsule products today, and Impax has FDA approval to market a fenofibrate capsule. Consolidated Indirect Purchaser Complaint, ¶ 51; Impax Counterclaims, ¶ 43. In addition, First Horizon has approval for a fenofibrate tablet (Triglide).

remain free to market their products along with every other rival cholesterol-regulating drug competing in the marketplace today. In this respect, the present case is factually and analytically similar to *Medtronic Minimed Inc. v. Smiths Med. MD Inc.*, 371 F. Supp. 2d 578 (D. Del. 2005) (Jordan, J.), where the plaintiff was not prevented by the defendant from making a competing product, but rather chose not to do so.

Second, Plaintiffs concede that the new TriCor products have different, enhanced features. As Plaintiffs admit in their pleadings, the Tablet Introduction represented an improvement over the previous capsule version in a number of respects. For example, it was a tablet rather than a capsule,<sup>10</sup> it had improved bioavailability which allowed it to contain a lower dosage of the active ingredient,<sup>11</sup> and it had a new indication to raise HDL.<sup>12</sup>

The next-generation NFE Tablet also contained additional improvements over its predecessor. It had further improved bioavailability, allowing an even lower dosage to be used,<sup>13</sup> and patients were no longer required to take the product with food to realize the full therapeutic benefits.<sup>14</sup>

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<sup>10</sup> See Teva Counterclaims, ¶ 71; Impax Counterclaims, ¶ 33; Walgreen Complaint, ¶ 51; CVS Complaint, ¶ 50; Consolidated Direct Purchaser Complaint, ¶ 79; Consolidated Indirect Purchaser Complaint, ¶ 53; Pacificare Complaint, ¶ 46.

<sup>11</sup> See Teva Counterclaims, ¶ 70; Impax Counterclaims, ¶ 33; Walgreen Complaint, ¶ 51; CVS Complaint, ¶ 50; Consolidated Direct Purchaser Complaint, ¶ 79; Consolidated Indirect Purchaser Complaint, ¶ 53; Pacificare Complaint, ¶ 46.

<sup>12</sup> See Teva Counterclaims, ¶ 71; Impax Counterclaims, ¶ 33; Walgreen Complaint, ¶ 63; CVS Complaint, ¶ 59; Consolidated Direct Purchaser Complaint, ¶¶ 87-88; Consolidated Indirect Purchaser Complaint, ¶ 53.

<sup>13</sup> See Teva Counterclaims, ¶ 86; Impax Counterclaims, ¶ 56; Walgreen Complaint, ¶ 111; CVS Complaint, ¶ 104; Consolidated Direct Purchaser Complaint, ¶ 107; Consolidated Indirect Purchaser Complaint, ¶ 73; Pacificare Complaint, ¶¶ 69-70.

<sup>14</sup> See Teva Counterclaims, ¶ 98; Impax Counterclaims, ¶ 59; Walgreen Complaint, ¶ 112; CVS Complaint, ¶ 105; Consolidated Direct Purchaser Complaint, ¶ 109; Consolidated Indirect Purchaser Complaint, ¶ 93. Some Plaintiffs concede that certain of the improvements to the NFE tablet were made possible by technology acquired from Elan, and allege that this acquisition was anticompetitive. See Walgreen Complaint, ¶¶ 112, 125. The allegation that the acquisition of technology from a non-competitor for the purpose of improving a product is anticompetitive does not state or support a claim under the antitrust laws.

Even Plaintiffs concede that one-third of the time patients taking the first-generation TriCor tablet were not taking the product with food, and thus not in compliance with the FDA-approved label.<sup>15</sup>

Plaintiffs attempt to ignore these product advances by focusing on one dimension of the products and asserting that the new products do not represent an improvement because, although the dosage of active ingredient is lower and the indications broader, they contain the “same medication used for the same indications” or are “bioequivalent,” meaning that patients end up with the same amount of active ingredient in the bloodstream with the same corresponding pharmacological effect. *See, e.g.*, Teva Counterclaims, ¶ 99; Walgreen Complaint, ¶ 51. Yet, the product differences that Plaintiffs acknowledge represent steps forward in patient convenience and compliance, ease of administration, and breadth of approved indications and usage under the FDA-approved label. Plaintiffs cannot – and do not – allege otherwise.

Having acknowledged product improvements, Plaintiffs resort to advocating a test under which the amount of product improvement is weighed against its potential exclusionary effects. Teva Counterclaims, ¶ 238. Plaintiffs’ allegations invite this Court to engage in precisely the type of post-hoc balancing that the cases and commentators note should be avoided. *See, e.g., Berkey*, 603 F.2d at 286-87 (refusing to evaluate the qualitative differences between the new product and the predecessor product); Hovenkamp, *Monopolization Offense, supra*, at 1046 (“The federal courts are simply not up to the job of balancing the gains from innovation against the losses from reduced competition.”). As Professor Areeda noted, Plaintiffs here must show that the Tablet Introduction and NFE Introduction were “absolutely no better” than the prior version. *See Areeda & Hovenkamp, supra*, at ¶ 776d. Having admitted the actual improvements, Plaintiffs’ complaints collapse.

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<sup>15</sup> Teva Counterclaims, ¶ 98.

Plaintiffs also appear to assert that the expanded label of increasing HDL for the Tablet Introduction should be ignored because Defendants could have elected to introduce their innovation in capsule form. Teva Counterclaims, ¶ 71. Plaintiffs' argument would require courts to regulate the time and manner of how a company must introduce new products to the market. Such claims have been rejected. *See Berkey*, 603 F.2d at 286 ("any firm, even a monopolist, may generally bring its products to market whenever and however it chooses"); 3A Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 658f2 (2000 & 2005 Supp.) ("Surely juries should not determine whether the defendant's product innovation could have moved along some alternative, 'less restrictive' path that would have injured the plaintiff less.").

**C. Abbott and Fournier Have No Duty to Maintain Discontinued Products in the Marketplace.**

In attempting to regulate competition to suit their own purposes, Plaintiffs also allege that, if a company introduces a new product, it has an affirmative obligation to continue selling the old one in order to assist a competitor. These allegations fail to support an antitrust claim. It is axiomatic that the antitrust laws impose no general duty to aid competitors. *See Trinko*, 540 U.S. at 410-411 (concluding that "Verizon's alleged insufficient assistance . . . to rivals is not a recognized antitrust claim under this court's refusal to deal precedents"); *Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 375 (7th Cir. 1986) ("[I]t is clear that a firm with lawful monopoly power has no general duty to help its competitors, whether by holding a price umbrella over their heads or by otherwise pulling its competitive punches."); *Medtronic*, 371 F. Supp. 2d at 588 ("With few, narrow exceptions . . . the antitrust laws contain 'no duty to aid competitors.'") (quoting *Trinko*, 540 U.S. at 411); 3A Areeda & Hovenkamp, *supra*, at ¶ 776d ("Even a monopolist is entitled to compete aggressively and to redesign its products in order to make them more attractive to its customers, without any duty to help other firms 'survive or expand.'").

Yet, this is precisely the theory that Plaintiffs have pled. Plaintiffs complain that, when Abbott stopped selling its fenofibrate capsules, it also “changed Abbott’s sales force and stopped detailing the capsule formulation in the market.” Teva Counterclaims, ¶ 70. Teva urges that this adversely affected its sales of generic versions of the old products because its business model relies on others to perform its marketing and sales function: Teva “does not employ – and, because of the workings of generic substitution and other realities of the pharmaceutical marketplace, should not need to employ – an extensive marketing department like those utilized by brand-name companies.” Teva Counterclaims, ¶ 79. This argument fails to state a claim for several reasons.

Abbott is under absolutely no duty to act as Teva’s sales force. Competitors are “expected to make their own way in the market, by advertising or other means of promotion.” *Olympia*, 797 F.2d at 377. The *Olympia* court further stated:

[A rival has] no right under antitrust law to take a free ride on its competitors’ sales force. You cannot conscript your competitor’s salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant. Advertising a competitor’s products free of charge is not a form of cooperation commonly found in competitive markets; it is the antithesis of competition.

*Id.* at 377-78.

Indeed, as a matter of law, a patent holder does not have to use *any* of its patented formulations. *See* 35 U.S.C. § 271(d)(4) (a patent owner cannot be found guilty of patent misuse by virtue of its refusal to use or license its patent); *Cont’l Paper Bag v. Eastern Paper Bag*, 210 U.S. 405, 429 (1908) (the holder of a patent has no obligation to use its patent rights at all: “[I]t is the privilege of any owner of property to use or not use it, without question of motive”; “[S]uch exclusion may be said to have been of the very essence of the right conferred by the patent”).

Plaintiffs’ theory apparently is that they should be able to dictate the sales and promotion activities of Abbott and Fournier – so that Teva and Impax can free-ride on the TriCor brand – to the

point of advocating a rule that would require Defendants to keep a particular TriCor product on the market for their convenience. No time limit is given for this “duty,” and its intrusiveness on the rights of the Defendants is obvious.<sup>16</sup>

For all of these reasons, Plaintiffs’ claims arising from Defendants’ decision to discontinue selling the old versions of TriCor fail as a matter of law.

**D. Truthful Communications to the NDDF Service Do Not Establish Cognizable Antitrust Claims and Are Otherwise Protected by the First Amendment.**

As a fallback to the theory that discontinuing old products is actionable, Plaintiffs allege that notifying NDDF of this fact can somehow be actionable. Any seller has a legitimate commercial interest in ensuring that potential purchasers have accurate information on the seller’s product line. If a seller has a right to discontinue selling a product, notifying the public of that action cannot provide the basis for a cause of action. Moreover, such a prohibition on admittedly truthful commercial speech would infringe Abbott’s First Amendment right of free speech. *See, e.g., Ibanez v. Florida Dep’t of Bus. and Prof. Reg., Bd. of Accountancy*, 512 U.S. 136, 142-43 (1994) (observing that the First Amendment protects truthful commercial speech; restrictions of such speech are permissible only to the extent they are narrowly tailored to advance a substantial state interest).

Plaintiffs concede in their pleadings that removal of the reference code for a previous formulation of TriCor does not foreclose Teva or Impax from selling fenofibrate products. Plaintiffs’

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<sup>16</sup> *See, e.g., Verizon Commc’n v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-416 (2004) (“The Sherman Act is . . . the Magna Carta of free enterprise, but it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.”) (citations omitted); *Morris Commc’n Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1295 (11th Cir. 2004) (“PGA met its business justification burden [in refusing to deal or cooperate with Morris] by showing that it sought to prevent Morris from ‘free-riding’ on PGA’s RTSS technology.”); *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 (1977) (holding that prevention of “free-riding” by competitors is a legitimate business purpose); *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1573 (11th Cir. 1991) (stating that it “is not a function of the antitrust laws” to equip plaintiffs with defendants’ competitive advantages).



complaint is that when there is no branded NDDF code to use as a reference, “[t]he generic drug loses its status as a generic and thus gets classified as a brand and can only be sold as a brand.” Teva Counterclaims, ¶ 96. In other words, because Abbott was no longer selling the older versions of TriCor, or alternatively did not conceal this fact from the market, Teva and Impax could not as easily free-ride by selling a generic version of that older product. Quite simply, Plaintiffs are asking this Court to allow them to “compete” without having to promote and sell their own product – something Teva candidly admits it is just unwilling to do. Teva Counterclaims, ¶ 79.

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For all these reasons, Plaintiffs’ allegations relating to the introduction of new products and discontinuance of old products, do not state a claim under Sections 1 or 2 of the Sherman Act.

### **III. Plaintiffs’ Allegations Of Wrongful Litigation Conduct Do Not State A Claim Under The Antitrust Laws.**

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#### **A. Defendants’ Litigation Is Immunized From Antitrust Challenge As A Matter Of Law Under The *Noerr-Pennington* Doctrine.**

Plaintiffs allege that Abbott and Fournier have violated Sections 1 and 2 of the Sherman Act through the filing and maintenance of certain lawsuits brought to enforce their patent rights. Specifically, Plaintiffs allege that the filing and prosecution of the suits in this Court attempting to enforce the Stamm patents were sham litigations. Walgreen, CVS, and the consolidated direct purchaser class also claim that the patent litigations in connection with the ‘726 patent and TriCor capsules (the “Capsule Litigations”) were sham litigations, although the actual defendants in those cases – Teva and Impax – do not.

#### **1. The *Noerr-Pennington* Standard.**

In *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (“*PRE*”), the Supreme Court adopted a two-part test to determine whether a lawsuit is a sham and therefore not immune to challenge under the antitrust laws. *PRE*, 508 U.S. at 60. First, “the lawsuit must

be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” *Id.* “Second, if the petition is objectively baseless (and only if it is objectively baseless), the Court is to look to the petitioner’s ‘subjective motivation’ . . . .” *Armstrong Surgical Ctr., Inc. v. Armstrong County Mem’l Hosp.*, 185 F.3d 154, 158 (3d Cir. 1999). Both prongs of this test must be met for a litigation to be held to be a sham.

As the Supreme Court made clear in *PRE*, objective baselessness is equated with the common law standard of probable cause, which “requires no more than a ‘reasonabl[e] belief that there is a *chance* that [a] claim *may* be held valid upon adjudication.’” *PRE*, 508 U.S. at 62-63 (emphasis added) (citations omitted). As this Court has noted elsewhere, “probable cause under *PRE* does not mean that a litigant is *certain* that it will prevail at trial. Rather, it requires no more than a *reasonable belief* that an allegation *may* be deemed valid.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 326 (D. Del. 2004) (emphasis in original). The critical issue in determining whether a claim is objectively baseless is not whether the asserted claim is indeed ultimately the correct position on the issue, but whether “no reasonable person would take the position” asserted by the litigant. *Miller Pipeline Corp. v. British Gas PLC*, 69 F. Supp. 2d 1129, 1142 (S.D. Ind. 1999)

#### **B. The Tablet Litigations.**

Plaintiffs attempt to plead around the *Noerr-Pennington* immunity through conclusory recitations of the sham litigation standard outlined in *PRE*, and by alleging that the Tablet Litigations were objectively baseless because (i) this Court granted summary judgment of non-infringement in favor of Teva and Impax on one of the three patents-in-suit; (ii) Abbott and Fournier performed no physical testing on the generic fenofibrate tablet samples provided to them by Teva and Impax before commencing litigation; (iii) Fournier committed inequitable conduct in obtaining certain patents and therefore knew that the patents would later be unenforceable; and (iv) the Defendants dismissed the Tablet Litigation



before trial. As described below, none of these allegations pleads a claim that circumvents *Noerr-Pennington*.

**1. This Court's Summary Judgment Rulings Demonstrate the Objective Reasonableness of the Tablet Litigation.**

Plaintiffs allege that the fact that Abbott and Fournier lost certain claims on summary judgment shows that their patent litigations were objectively baseless. However, this Court can look to the record and its own rulings in this proceeding (*i.e.*, the tablet litigations from which this antitrust case derived as a counterclaim), and therefore can take judicial notice of whether Abbott's and Fournier's overall position was such that "no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. Indeed, this Court can take judicial notice that it found triable issues of fact relating to the patents in this proceeding. *See Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221 (S.D.N.Y. 2002) (the court took judicial notice of the patent litigation in a related action before a different court).

*Twin City Bakery* is closely on point. Following patent litigation between a branded pharmaceutical company and ten generic drug manufacturers, plaintiffs brought a Section 2 claim alleging that the defendants instituted sham patent litigations to get 30-month stays under the Hatch-Waxman Act and thereby delay competition from generic drugs. Some of the patent claims were upheld while others were rejected. *Id.* at 224. The judge in the antitrust case ruled that, even on a motion to dismiss, it could take notice of the orders of the judge in the patent litigation that were referenced in the Amended Complaint, as well as "other orders and related public records in the case." *Id.* Because the judge in the patent litigation had upheld some of the claims, the court granted the motion to dismiss the antitrust claims, stating that the patent case determinations "allowing claims of infringement of four of the six asserted patents to proceed beyond summary judgment, and two of the four to proceed through trial,

preclude any contention that defendants' litigation is so baseless as not to warrant *Noerr-Pennington* immunity." *Id.*

In the preceding patent litigation, Teva and Impax collectively filed nine summary judgment motions. This Court rejected eight of those motions all or in part. The only motion that was granted in full was decided on the basis of the Court's construction of one claim term (hydrophilic polymer). During the claim construction process, the Court ruled as a matter of law that Abbott and Fournier correctly construed six of eight claim terms in dispute.<sup>17</sup> At the end of extensive motion practice, Teva and Impax faced trial on six claims of the '881 patent and claim 6 of the '405 patent.

For the same reasons underlying the court's decision in *Twin City Bakery*, this Court should take notice of Abbott's and Fournier's successes in the patent litigations in determining that those litigations were not objectively baseless, and find that they are therefore immunized from challenge under *Noerr-Pennington*.<sup>18</sup>

## 2. Product Testing.

Teva alleges that the failure to perform dissolution tests on Teva's product provides a basis for asserting that a claim of infringement was objectively baseless. There is no requirement that the Defendants conduct any dissolution testing of a generic product before asserting their patents. *Q-Pharma Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1302 (Fed. Cir. 2004) (holding that a valid infringement analysis "can simply consist of a good faith, informed comparison of the claims of a patent against the

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<sup>17</sup> See *Abbott Labs. v. Teva Pharm., Inc.*, No. 02-1512-KAJ (consolidated), 2005 WL 1026746, at \*2 (D. Del. Apr. 22, 2005) (attached as Exhibit 5).

<sup>18</sup> Moreover, as the court in *Twin City Bakery* found, successfully opposing a summary judgment motion can be viewed as validating a plaintiff's objective good faith. See *Harris Custom Builders v. Hoffmeyer*, 834 F. Supp. 256, 261-62 (N.D. Ill. 1993) (action sufficient to survive summary judgment cannot be a sham); *Gen-Probe, Inc. v. Amoco Corp., Inc.*, 926 F. Supp. 948, 958 (S.D. Cal. 1996) ("A denial of summary judgment means that the nonmoving party has produced enough evidence that a rational jury could find in its favor. A party with sufficient evidence to support a jury finding in its favor has probable cause to bring a lawsuit.").

accused subject matter.”); *see also Pennpac Int'l, Inc. v. Rotonics Mfg., Inc.*, No. 99-2890, 2001 WL 569264, at \*6 (E.D. Pa. May 25, 2001) (holding an enforcement action was not a sham despite absence of physical examination of infringing product, when patentee instead conducted visual and diagrammatic comparisons, aided by patent counsel) (attached as Exhibit 6).

More importantly, Teva implicitly concedes that its fenofibrate tablets infringe at least some claims of the ‘881 patent. Teva coyly answers that Teva “does not infringe any *valid* claim of the ‘881 patent.” Teva’s Answer, ¶ 17 (emphasis added); *see also id.* ¶ 15. Indeed, the Court found triable issues of fact as to the ‘405 and ‘881 patents on which Teva moved for summary judgments based on its proposed claim construction.

Accordingly, the allegation that Defendants did not perform physical tests on the infringing tablets before bringing the patent litigations does not support a claim that there was no objective basis to assert infringement.

### **3. Inequitable Conduct.**

Plaintiffs also allege that the Tablet Litigations brought by Abbott and Fournier were objectively baseless because Defendants knew that the patents were improperly obtained through inequitable conduct. Plaintiffs are inappropriately attempting to use a sham litigation claim to plead an antitrust violation based on inequitable conduct, rather than meet the requirements of *Walker Process*.

In the *Walker Process* case itself, the Supreme Court set a high bar for plaintiffs bringing litigation based on enforcement of patent rights, requiring fraud on the patent office. 382 U.S. at 174. As Justice Harlan’s concurring opinion clarified, this standard was deliberately set high so as not to “chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits.” *Id.* at 180. Subsequent courts considering whether to allow antitrust claims on the basis of inequitable conduct have rejected such an approach as diluting the high

standard set by the Supreme Court in *Walker Process*. The Eighth Circuit considered this very issue and categorically rejected the attempted use of inequitable conduct as the basis for an antitrust claim:

Berkley's attempt to base its antitrust counterclaim on "inequitable conduct" has no basis in law. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, . . . , the Supreme Court ruled that enforcement of a patent procured by fraud on the PTO may violate § 2 of the Sherman Act if other elements necessary to a § 2 case are present. Admitting that *Walker Process* and its progeny speak only of fraud, and acknowledging that no court has recognized "inequitable conduct" as a basis for an action under Section 2 of the Sherman Act, Berkley nevertheless argues that it is as much a violation of the Act "for a patent owner to enforce an 'unenforceable' patent against potential competitors as it is to enforce an 'invalid' patent." We disagree.

*E. I. du Pont de Nemours & Co. v. Berkley and Co., Inc.*, 620 F.2d 1247, 1273-74 (8th Cir. 1980) (footnote omitted). The Federal Circuit reached the same result in *Argus Chem. Corp. v. Fibre Glass-Evercoat Co., Inc.*, 812 F.2d 1381, 1384 (Fed. Cir. 1987) (rejecting the argument that the inequitable conduct standard should be applied in determining whether misconduct before the PTO could provide the basis for a charge of monopolization).<sup>19</sup>

Even putting aside the question of the proper legal standard, Plaintiffs' inequitable conduct claim tries to twist *PRE*'s objective standard into a purely subjective one. Plaintiffs' argument in essence is that the patent litigations were objectively baseless because Abbott and Fournier knew – subjectively – that their patents would subsequently be found invalid under the inequitable conduct doctrine. The *PRE* test is intended to allow the courts to review the merits of the litigation without inquiring into the subjective intent of the litigants. As described above, any objective review of the

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<sup>19</sup> In *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F. 3d 1059 (Fed. Cir. 1998), the Federal Circuit affirmed the district court's finding of a *Walker Process* violation without proof that the plaintiff's claims satisfied the objectively baseless test of *PRE* and in doing so suggested that the two doctrines were independent bases to strip the patent holder of antitrust immunity. Given the Supreme Court's teachings about precisely what constitutes an actionable antitrust claim in the context of an alleged fraud on the Patent Office, the Federal Circuit opinion cannot be read to create a different standard for the same type of conduct.

Tablet Litigations must come to the conclusion that the suits were not baseless, particularly given the rulings shaping the matter for trial.

The only patent that Teva and Impax allege was obtained through *Walker Process* fraud is the '881 patent. As discussed below, however, Teva and Impax do not adequately plead antitrust injury with respect to the enforcement of the '881 patent and therefore their *Walker Process* claims fail as a matter of law. The other Plaintiffs, all direct or indirect purchasers, lack standing to bring a *Walker Process* claim.<sup>20</sup>

Defendants are unaware of any case that has allowed a plaintiff to circumvent the elements laid down by the Supreme Court in *Walker Process* to plead an antitrust claim solely based on inequitable conduct before the PTO. Accordingly, no Plaintiff should be allowed to bring what amounts to a *Walker Process* claim, based on a lower showing of inequitable conduct before the PTO, simply by couching their claim as predicated on sham litigation. To hold otherwise would vitiate the rationale underlying *Walker Process*, which requires a higher showing of culpability before allowing plaintiffs to expose a defendant to antitrust liability and treble damages.

#### **4. The Dismissal of the Tablet Litigation Patent Claims.**

Defendants' voluntary dismissal of the patent claims cannot form the basis of a sham litigation claim. The dismissal of the patent claims prior to trial does not indicate that the claims were without merit. Indeed, as discussed above, the Court's claim construction and summary judgment rulings in the patent cases demonstrate that Abbott's and Fournier's infringement claims were not objectively baseless.

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<sup>20</sup> See, e.g., *Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704, 714 (9th Cir. 2003) ("*Walker Process* . . . requires that to have standing to sue, a company which wishes to enter the market demonstrate that it was a potential competitor . . ."); *In re Remeron*, 335 F. Supp. 2d 522, 528-29 (D.N.J. 2004) (holding that a plaintiff only had standing if the defendant sought to enforce the patent against plaintiff, or the plaintiff had a reasonable basis for believing defendant would attempt to do so).

As acknowledged by Plaintiffs, Defendants introduced the NFE tablets in December of 2004, and the new product had long been sold by the June 2005 trial date. Teva Counterclaims, ¶¶ 86-87. At that time, the litigation involved attempts by Teva and Impax to introduce generic copies of the tablet product that Abbott had already discontinued, and therefore the litigation was moot from a practical standpoint. Moreover, had Abbott and Fournier proceeded to trial and prevailed on the claims regarding the discontinued product, Teva and Impax would still be free to file ANDAs against the new NFE product and challenge any listed patents all over again. Thus, all parties concerned elected to resolve the patent dispute before trial, and accordingly reached settlement.

### **C. The Capsule Litigations.**

Certain of the Plaintiffs allege, without any foundation, that the Capsule Litigations were objectively baseless. This allegation is insupportable for a number of reasons and should be dismissed. Teva and Impax – the only Plaintiffs who were parties to the Capsule Litigations – did not allege at the time that Abbott’s and Fournier’s claims in those litigations were objectively baseless and do not so allege today.<sup>21</sup>

The fact that Abbott and Fournier lost on a summary judgment motion does not mean that the litigation was objectively baseless. *See, e.g., PRE*, 508 U.S. at 64-65 (noting that the legal theory advanced, while ultimately rejected, was plausible); *Covad Commc’n Co. v. Bell Atl. Corp.*, 398 F.3d 666, 677 (D.C. Cir. 2005) (infringement action lost on summary judgment was not a sham because patentee “advanced reasonable arguments that [the Federal Circuit and district court] went to some lengths to

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<sup>21</sup> In fact, because such an allegation could only be brought by Teva and Impax as a compulsory counterclaim, they are barred from asserting such a claim at this late date. *See Critical-Vac Filtration Corp. v. Minuteman Int’l, Inc.*, 233 F.3d 697, 700 (2d Cir. 2000) (holding that such antitrust counterclaims are compulsory because “[a]n obvious ‘logical relationship’ exists between [those] claims and the issues addressed by the earlier patent infringement suit . . .”), *cert. denied*, 532 U.S. 1019 (2001); *Genentech, Inc. v. Regents of the Univ. of California*, 143 F.3d 1446, 1456 (Fed. Cir. 1998) (affirming district court’s determination that a later-filed antitrust claim was a compulsory counterclaim to an earlier patent suit), *cert. granted, judgment vacated and remanded on other grounds*, 527 U.S. 1031 (1999).



reject.”). This is precisely the type of after-the-fact argument the Supreme Court cautioned against when it held that courts must “resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation.” *PRE*, 508 U.S. at 61 n.5 (internal quotation marks omitted).

Moreover, this Court can take notice of the Federal Circuit decision that discusses the key issues on which that litigation turned, which clearly shows that Abbott and Fournier had probable cause to bring that litigation. For example, the parties had legitimate disputes over (i) whether granulation is a micronization step; and (ii) whether co-micronization means fenofibrate and a surfactant in the presence or absence of other surfactants. A reading of the published opinion alone makes clear that Abbott’s and Fournier’s arguments on these issues were clearly not so baseless that “no reasonable person would take the position” that they advocated. *See Miller, supra*, 69 F. Supp. 2d at 1142.

#### **D. The Orange Book Listing Does Not State A Claim.**

Teva alleges that Abbott improperly listed the Stamm patents in the Orange Book, and claims that this violates Section 2 of the Sherman Act. Teva concedes that a patent can be listed in the Orange Book if it “claims the drug . . . or a method of using such drug,” but Teva does not allege that any listed patents fail to meet these requirements. Teva Counterclaims, ¶ 183. Therefore, Teva’s only claim with respect to the Orange Book listing is its allegation that Defendants knew that the listed patents would later be held unenforceable because they had been obtained through inequitable conduct.<sup>22</sup> This appears

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<sup>22</sup> To the extent that Teva may be alleging that it has the right to challenge the listing of a patent in the Orange Book, that claim fails as a matter of law because private plaintiffs have no right to bring such an action. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d. Cir. 1999) (“It is well settled that the FDCA creates no private right of action.”); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1331 (Fed. Cir. 2001) (there is no provision “allowing an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent.”), *cert. denied*, 537 U.S. 941 (2002).